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Chapter 49: Vaccines, Toxoids, and Other Immunobiologics

INTRODUCTION

- *Vaccines* are substances administered to generate an active immunity. They can be live attenuated or inactivated, or made with mRNA.
- *Adjuvants* are chemicals that stimulate a strong but short-lived inflammatory response, which strengthens the immune response to the antigen.
- *Immunoglobulins (Igs)* are sterile solutions containing antibody derived from human (Ig) sources.

VACCINE RECOMMENDATIONS

- The latest vaccine schedules can be found at https://www.cdc.gov/vaccines/?CDC_AAref_Val=https://www.cdc.gov/vaccines/schedules/hcp/index.html.
- The childhood, adolescent, and adult immunization schedules are updated frequently and published annually. Recommendations for the use of influenza vaccine are issued annually. Healthcare providers involved in primary care and immunization delivery must keep themselves abreast of these changes in a systematic way. Electronic newsletters and browsing reliable websites are efficient methods for obtaining information (**Table 49-1**).
- In general, inactivated and live-attenuated vaccines can be administered simultaneously at separate sites. If two or more inactivated vaccines cannot be administered simultaneously, they can be administered without regard to spacing between doses. Inactivated and live vaccines can be administered simultaneously or, if they cannot be administered simultaneously, at any interval between doses. If live vaccines are not administered simultaneously, their administration should be separated by at least 4 weeks.
- Administration of live vaccines, such as rubella or varicella, is deferred until pregnancy is completed and is routinely recommended for those who do not have evidence of immunity prior to hospital discharge. These live vaccines can be administered without regard to administration of Rho(D) Ig (RDIg) in the postpartum period. Tetanus, diphtheria, acellular pertussis vaccine (Tdap) should be administered during the late second trimester or third trimester of pregnancy.
- Severely immunocompromised individuals should not receive live vaccines.
- Patients with chronic pulmonary, renal, hepatic, or metabolic disease and who are not receiving immunosuppressants may receive live-attenuated and killed vaccines, as well as toxoids.
- Patients with active malignant disease may receive killed vaccines or toxoids but should not be given live vaccines. Live virus vaccines may be administered to persons with leukemia who have not received chemotherapy for at least 3 months.
- If a person has been receiving high-dose corticosteroids or has had a course lasting longer than 2 weeks, then at least 1 month should pass before immunization with live virus vaccines.
- Patients with HIV infection may have suboptimal immune responses to live and inactivated vaccines.
- Whenever possible, solid organ transplant patients should be immunized before transplantation. Live vaccines generally are not given after transplantation. Patients who have undergone hematopoietic stem cell transplantation should be reimmunized with inactivated vaccines beginning approximately 6 months after transplantation. Pneumococcal vaccines, meningococcal vaccines, and *Haemophilus influenzae* type b (Hib) vaccines are recommended. Measles, mumps, and rubella (MMR) and varicella vaccines can be administered at 24 months.

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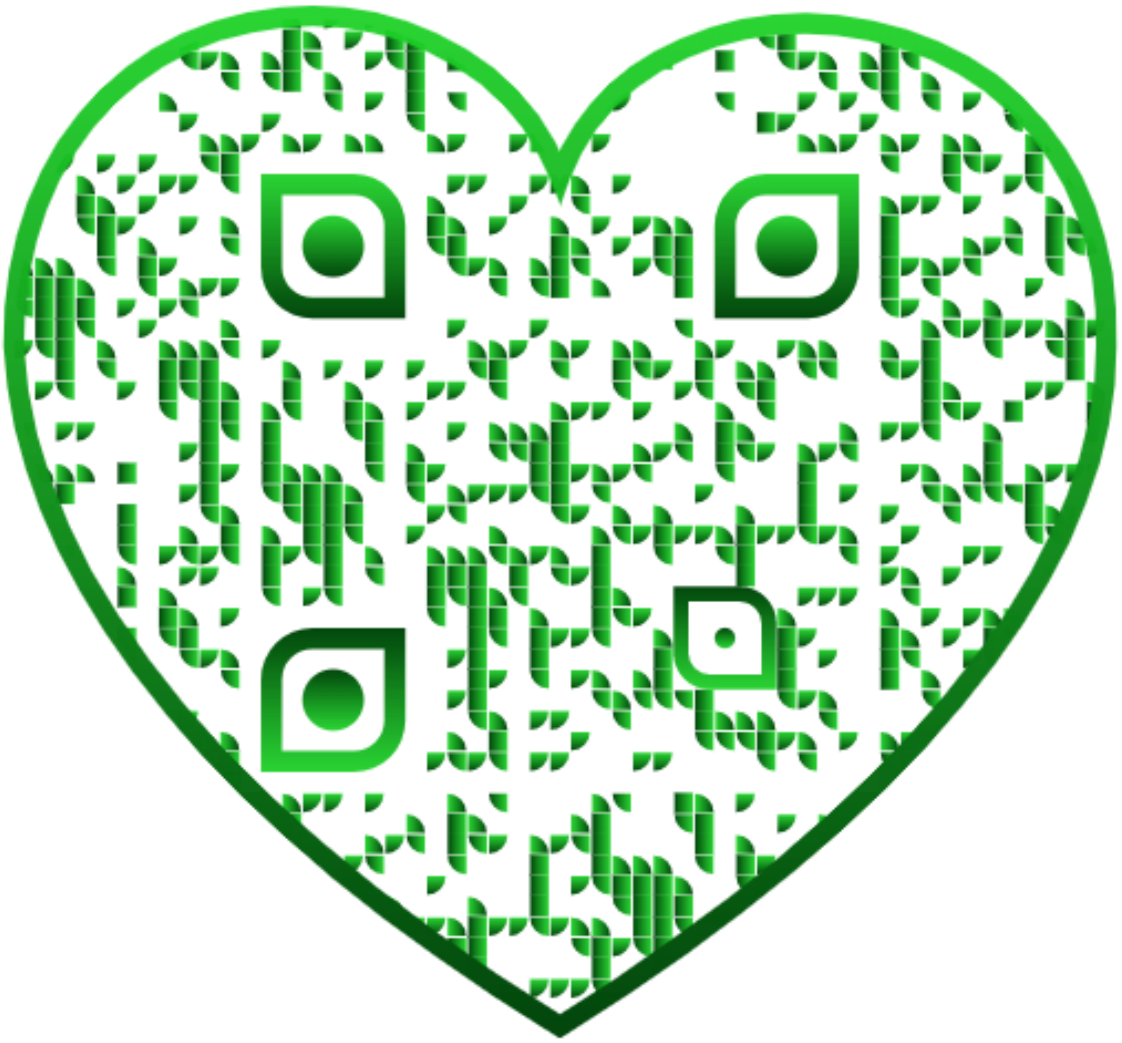

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TABLE 49-1

Web Resources for Vaccine Information

Recommended Internet Sites for Vaccine Information	
http://www.cdc.gov/vaccines/	Vaccines and Immunizations
	Centers for Disease Control and Prevention
www.immunize.org	Immunization Action Coalition
www.nfid.org/	National Foundation for Infectious Diseases
www.cdc.gov/mmwr/	Morbidity and Mortality Weekly Report
http://www.nationalacademies.org/hmd/	The National Academies of Sciences, Engineering, and Medicine. Health and Medicine Division
http://www.hrsa.gov/vaccinecompensation/	Vaccine Injury Compensation Program
http://www.chop.edu/centers-programs/vaccine-education-center/	Vaccine Education Center
	Children's Hospital of Philadelphia
https://vaers.hhs.gov/index.html	Vaccine Adverse Event Reporting System
Recommended Electronic Newsletters	
www.immunize.org/express	The Immunization Action Coalition's newsletter
www.cdc.gov/mmwr/	Morbidity and Mortality Weekly Report

DIPHTHERIA TOXOID ADSORBED AND DIPHTHERIA ANTITOXIN

- Two strengths of diphtheria toxoid are available: pediatric strength (D) and adult strength (d), which contain less antigen. Primary immunization with D is indicated for children older than 6 weeks. Generally, D is given along with tetanus and acellular pertussis (DTaP) vaccines at 2, 4, and 6 months of age and then at 15–18 months and 4–6 years of age. Booster doses should be given every 10 years.
- For nonimmunized adults, a complete three-dose series of diphtheria toxoid should be administered, with the first two doses given at least 4 weeks apart and the third dose 6–12 months after the second. One dose in the series should be Tdap. The combined preparation, tetanus–diphtheria (Td), is recommended in adults because it contains less diphtheria toxoid than DTaP, with fewer reactions to the diphtheria component. Booster doses of Td or Tdap are given every 10 years.
- Adverse effects to diphtheria toxoid include mild-to-moderate tenderness, erythema, and induration at the injection site.

TETANUS TOXOID, TETANUS TOXOID ADSORBED, AND TETANUS IMMUNOGLOBULIN

- In children, primary immunization against tetanus is usually done in conjunction with diphtheria and pertussis vaccination using DTaP or a combination vaccine that includes other antigens, and is recommended at 2, 4, 6, and 15–18 months of age.

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- In children 7 years and older and in adults who have not been previously immunized, a series of three 0.5-mL doses of Td is administered intramuscularly (IM) initially. The first two doses are given 1–2 months after the second dose and the third dose 6–12 months after the second dose. Boosters are recommended every 10 years.
- Tetanus Ig (TIg) is used to provide passive tetanus immunization after the occurrence of traumatic wounds in nonimmunized or suboptimally immunized persons (**Table 49-2**). A dose of 250–500 units is administered IM. When administered with tetanus toxoid, separate sites for administration should be used.
- TIg is also used for the treatment of tetanus. In this setting, a single dose of 3000–6000 units is administered IM.

TABLE 49-2

Tetanus Prophylaxis

Vaccination History	Clean, Minor Wounds		All Other Wounds	
	Td[a]	TIg	Td or Tdap[a]	TIg
Unknown or fewer than three doses	Yes	No	Yes	Yes
Three or more doses	No[a,b]	No	No[a,c]	No

[a]A single dose of Tdap should be used for the next dose of tetanus–diphtheria toxoid for individuals aged >10 years.

[b]Yes, if more than 10 years since last dose.

[c]Yes, if more than 5 years since last dose.

SARS CORONAVIRUS-19 VACCINES

- See Chapter 34, for coronavirus-19 vaccines.

HAEMOPHILUS INFLUENZAE TYPE B VACCINES

- Hib conjugate vaccines are indicated for routine use in all infants and children younger than 5 years.
- The primary series of Hib vaccination consists of 0.5-mL IM doses at 2, 4, and 6 months of age. A booster dose is recommended at age 12–15 months.
- For infants 7–11 months of age who have not been vaccinated, three doses of Hib vaccine should be given: two doses spaced 4 weeks apart and then a booster dose at age 12–15 months (but at least 8 weeks since the second dose). For unvaccinated children ages 12–14 months, two doses should be given, with an interval of 2 months between doses. In a child older than 15 months, a single dose of any of the vaccine preparations is indicated.

HEPATITIS VACCINES

- Information on hepatitis vaccines can be found in Chapter 25.

HUMAN PAPILLOMAVIRUS VACCINE

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- The Advisory Committee on Immunization Practices (ACIP) recommends human papillomavirus (HPV) vaccine for the prevention of HPV-related disease in individuals aged 9–26 years. Individuals who start the HPV series between the ages of 9 and 14 years should receive two doses separated by 6 months. This vaccine is administered as a three-dose series using a schedule of 0, 1–2, and 6 months for individuals who start the series at age 15 years or older. The vaccines are recommended for adolescents aged 11–12 years and catch-up immunization for individuals aged 13–26 years.
- The ACIP recommended shared clinical decision-making for HPV vaccine for individuals aged 27–45 years.
- The vaccine is well tolerated, with injection site reactions and headache and fatigue occurring as commonly as in placebo groups.

INFLUENZA VIRUS VACCINE

- See Chapter 40 for information regarding influenza vaccination.

MEASLES VACCINE

- Measles vaccine is a live-attenuated vaccine that is administered for primary immunization to persons 12–15 months of age or older, usually as a combination of MMR. A second dose is recommended at 4–6 years of age.
- Measles-containing vaccine should not be given to pregnant females or immunosuppressed individuals. Adults with HIV infection who have no evidence of measles immunity should be immunized as long as they are not severely immunocompromised.
- The vaccine should not be given within 4 weeks of any other live vaccine unless the vaccine is given on the same day (as with the MMR vaccine).
- Measles vaccine is indicated in all persons born after 1956 or in those who lack documentation of wild virus infection by either history or antibody titers.

MENINGOCOCCAL VACCINES

- There are two meningococcal (MenACWY) conjugate vaccines for individuals aged 9 months to 55 years old (MenQuadfi) or 2 months to 55 years old (Menveo). They are recommended for all children 11–12 years old, with a second dose at 16 years of age.
- Reimmunization at 5-year intervals is recommended for individuals who are at high risk.

MUMPS VACCINE

- The live attenuated vaccine (usually given in conjunction with measles and rubella as MMR and with varicella as MMRV) is given beginning at age 12–15 months, with a second dose prior to entry into elementary school.
- Two doses of mumps vaccine are recommended for school-age children, international travelers, students in post–high school educational institutions, and healthcare workers born after 1956.
- Postexposure vaccination is of no benefit.
- Mumps vaccine should not be given to pregnant women or immunosuppressed patients.

PERTUSSIS VACCINE

- Pertussis vaccine is usually administered in combination with diphtheria and tetanus toxoids (as DTaP or as acellular pertussis as Tdap).
- The primary immunization series for pertussis vaccine consists of four doses given at ages 2, 4, 6, and 15–18 months. A booster dose is recommended at age 4–6 years. Administration of an acellular pertussis-containing vaccine (Tdap) is also recommended for adolescents once between ages 11 and 18 years and a single dose of Tdap should be administered to all adults.

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- Tdap should be administered to persons in their late second or third trimester of pregnancy.
- Systemic reactions, such as moderate fever, occur in 3%–5% of those receiving vaccines. Rarely, high fever, febrile seizures, persistent crying spells, and hypotonic hyporesponsive episodes occur after vaccination.

PNEUMOCOCCAL VACCINES

- Three pneumococcal conjugate vaccine preparations, PCV13, PCV15, and PCV20, and a 23-valent pneumococcal polysaccharide vaccine (PPSV23) are available. The vaccines have different indications and are not interchangeable (**Table 49-3**).
- Pneumococcal polysaccharide vaccine (Pneumovax 23) is a mixture of highly purified capsular polysaccharides from 23 of the most prevalent or invasive types of *Streptococcus pneumoniae* seen in the United States. The vaccine is administered IM or subcutaneously as a single 0.5-mL dose.
- PCV13 or PCV15 valent is administered as a 0.5-mL IM injection at 2, 4, and 6 months of age and between 12 and 15 months of age. A single dose of PCV13 or PCV15 should be administered to children aged 6–18 years with sickle cell disease or splenic dysfunction, HIV infection, immunocompromising conditions, cochlear implant, or cerebral spinal fluid leak.

TABLE 49-3

Pneumococcal Vaccines Use in Adults

Vaccine-Naive Adults Aged 19–64 Years PCV15 followed by PPSV23 or PCV20
PCV13-Immunized Adults Aged 19–64 Years PCV20 or PPSV23 which should be repeated after a 5-year interval
PPSV23-Immunized Adults Aged 19–64 Years PCV15 or PCV20 at least 1 year after last dose of PPSV23
PCV13 + PPSV23-Immunized Adults Aged 19–64 Years PCV20 or PPSV23 at least 5 years after last pneumococcal vaccine
PCV13 + 2 Doses of PPSV23-Immunized Adults Aged 19–64 Years PCV20 at least 5 years after last pneumococcal vaccine
Indications for PCV20 or PCV15 Followed by PPSV23 for Adults 19–64 Years Immunocompromising conditions[a] Functional or anatomic asplenia Sickle cell disease or other hemoglobinopathies Congenital or acquired immunodeficiencies HIV infection Chronic renal failure or nephrotic syndrome Leukemias, lymphomas, Hodgkin's lymphoma Generalized malignancy Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids or radiation therapy Solid organ transplantation Multiple myeloma High-risk medical conditions[b]

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	Chronic heart disease Chronic liver disease Chronic lung disease Diabetes mellitus Alcoholism Cigarette smoking
Vaccine-Naive Adults Aged ≥65 Years	PCV15 followed by PPSV23 or PCV20
PCV13-Immunized Adults Aged ≥65 Years	PCV20 or PPSV23
PPSV23-Immunized Adults Aged ≥65 Years	PCV15 or PCV20 at least 1 year after last dose of PPSV23
PCV13 + PPSV23-Immunized Adults Aged ≥65 Years but No Dose after Age 65 Years	PCV20 or PPSV23 at least 5 years after last pneumococcal vaccine
PCV13 + PPSV23-Immunized Adults Aged ≥65 Years and PPSV23 Administered after Age 65 Years	Shared clinical decision-making, PCV20 at least 5 years after last pneumococcal vaccine

PCV20, 20-valent pneumococcal conjugate vaccine; PCV15, 15-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine.

[a]If PCV15 is used for those with high-risk medical conditions, administer PPSV23 12 months later.

[b]If PCV15 is used for immunocompromising conditions, administer PPSV23 8 weeks later.

POLIOVIRUS VACCINES

- Two types of trivalent poliovirus vaccines are currently licensed for distribution in the United States: an enhanced inactivated poliovirus vaccine (IPV) and a live-attenuated, oral poliovirus vaccine (OPV). IPV is the recommended vaccine for the primary series and booster dose for children in the United States, whereas OPV is recommended in areas of the world that have circulating poliovirus.
- IPV is given to children ages 2, 4, and 6–18 months and 4–6 years. Primary poliomyelitis immunization is recommended for all children and young adults up to age 18 years. Allergies to any component of IPV, including streptomycin, polymyxin B, and neomycin, are contraindications to vaccine use.
- OPV will continue to be used in areas of the world that have circulating poliovirus.

RUBELLA VACCINE

- The vaccine is indicated for children older than 1 year of age. The vaccine is given with measles and mumps vaccines (MMR) at 12–15 months of age, then at 4–6 years.
- The vaccine should not be given to immunosuppressed individuals, although MMR vaccine should be administered to young children with HIV

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without evidence of immunity.

- The rubella vaccine has never been associated with congenital rubella syndrome, but its use during pregnancy is contraindicated. However, routine pregnancy testing prior to vaccination is not recommended. Vaccine candidates should be counseled not to become pregnant for 4 weeks following vaccination.

VARICELLA VACCINE

- Varicella virus vaccine is recommended for all children 12–15 months of age, with a second dose between 4 and 6 years of age. Two doses separated by 4–8 weeks should be administered to anyone who lacks immunity to varicella.

  ✓ The vaccine is contraindicated in immunosuppressed or pregnant patients. An exception is children with asymptomatic or mildly symptomatic HIV infection, who should receive two doses of varicella vaccine 3 months apart.

  ✓ Children with humoral immune deficiencies may be immunized.

ZOSTER VACCINE

- A recombinant zoster vaccine (RZV) with an adjuvant is recommended by the ACIP for use in immunocompetent individuals aged 50 years and older and immunocompromised individuals aged 19 years and older as a two-dose series at 0 and 2–6 months. The RZV is 91% effective for preventing zoster.

- Almost 80% of those who receive the recombinant vaccine report injection site pain, with 9% of those reporting injection site reactions that interfere with their normal activities.

IMMUNOGLOBULIN

- Ig is available as both intramuscular (IGIM) and intravenous (IGIV) preparations.

- **Table 49-4** lists the suggested dosages for IGIM in various disease states.

- The uses for IGIV are as follows:

  ✓ Primary immunodeficiency states, including both antibody deficiencies and combined deficiencies.

  ✓ Idiopathic thrombocytopenia.

  ✓ Chronic lymphocytic leukemia in patients who have had a serious bacterial infection.

  ✓ Kawasaki disease (mucocutaneous lymph node syndrome).

  ✓ Pediatric HIV infection.

  ✓ Allogeneic bone marrow transplant.

  ✓ Chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy.

  ✓ Multifocal motor neuropathy.

  ✓ Kidney transplantation involving a recipient with high antibody concentrations or an ABO-incompatible donor.

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TABLE 49-4

Indications and Dosage of Intramuscular Immunoglobulin in Infectious Diseases

Primary immunodeficiency states	1.2 mL/kg IM, then 0.6 mL/kg every 2–4 weeks
Hepatitis A exposure	0.02 mL/kg IM within 2 weeks if <1 year or >39 years of age
Hepatitis A prophylaxis	0.02 mL/kg IM for exposure <3 months' duration
	0.06 mL/kg IM for exposure up to 5 months' duration
Hepatitis B exposure	0.06 mL/kg (hepatitis B immune globulin preferred in known exposures)
Measles exposure	0.5 mL/kg (maximum dose 15 mL) as soon as possible

RHO(D) IMMUNOGLOBULIN

- RDIg suppresses the antibody response and formation of anti-Rho(D) in Rho(D)-negative, D^u-negative women exposed to Rho(D)-positive blood and prevents the future chance of erythroblastosis fetalis in subsequent pregnancies with a Rho(D)-positive fetus.
- RDIg, when administered IM within 72 hours of delivery of a full-term infant, reduces active antibody formation from 1% to 0.2%. The dosage of RDIg varies with the indication. A standard dose of 300 mcg is given within 72 hours of a term delivery. Occasionally, when the fetus is known to be Rho(D)-positive, a 300-mcg dose is given at 28 weeks' gestation and within 72 hours after delivery.
- RDIg is also used in the case of a premenopausal woman who is Rho(D)-negative and has inadvertently received Rho(D)-positive blood or blood products.
- RDIg may be used after abortion, miscarriage, amniocentesis, or abdominal trauma. For postpregnancy termination occurring up to 13 weeks' gestation, one microdose (50 mcg) vial is given within 72 hours. For pregnancy termination after 13 weeks, one standard dose (300 mcg) is given within 72 hours. In other circumstances, such as in abdominal trauma, amniocentesis, or transfusion accidents, the dosage (number of standard dose vials) is based on the estimated packed red blood cell volume of fetal/maternal hemorrhage divided by 15. RDIg is administered IM only.

See Chapter 152, Vaccines and Immunoglobulins, authored by Mary S. Hayney, for a more detailed discussion of this topic.

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